

## **REMARKS**

### **Summary of Status of Amendments**

Upon entry of this amendment, claim 1 will be amended. Therefore, claims 1-8 are all the claims pending in the application.

Applicants note that claim 1 has been amended to more clearly recite the claimed subject matter. Applicants note that claim 1 is amended herein to include the recitation “wherein each base of interest in the sample polynucleotide is identified by one probe complementary to the base sequence of interest.” Support for this amendment may be found throughout the originally filed specification, for example, at page 3, lines 2-8, Figure 2(B), page 11, lines 4-15, Figure 1(E), and Example 1 at page 14, lines 9-22.

No new matter is added.

### **Drawings**

Applicants express appreciation toward the Examiner for acceptance of the drawings filed March 17, 2004, and December 7, 2006.

### **Claim of Priority**

Applicants thank the Examiner for acknowledging his error regarding the claim of priority and has corrected the record to reflect that no priority claim is made.

### **Rejection Under § 102(b)**

Claims 1 and 3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Somers et al. (Nucleic Acids Research 22(22): 4840-4841 (1994); hereinafter “Somers”).

The Office asserts that Somers teaches a method consisting essentially of the limitations recited in claims 1 and 3. With regard to claim 3, the Office asserts that Somers teaches using two probes (i.e., plural kinds of probe polynucleotides) to detect plural base sequences of interest (i.e., wild type and mutant). The Office asserts that it is the Applicants’ burden to establish what

step is practiced in an alleged prior art method that is excluded from the claimed invention by the “consisting essentially of” language.

In response, and as discussed in Applicants’ Amendment filed December 7, 2006, Somers is directed to the use of Exonuclease-Amplification Capture Coupled Technique (“EXACCT”) which produces two single-stranded DNA which are each hybridized to two different detection probes; a biotinylated capture probe and a digoxigenin labeled probe. Somers teaches a method of detection whereby two probes are required for the detection of one contiguous base sequence.

In contrast, the claimed invention may be implemented with multiple probes to detect multiple, non-contiguous base sequences of interest “wherein each base sequence of interest in the sample polynucleotide is identified by one probe complementary to the base sequence of interest.” Support for this amendment may be found throughout the original specification, for example, at page 3, lines 2-8, Figure 2(B), page 11, lines 4-15, Figure 1(E), and Example 1 at page 14, lines 9-22.

Therefore, the claimed method is different from Somers because the claimed method can identify a base sequence of interest with only one probe while Somers requires at least two probes to detect one sequence.

Accordingly, reconsideration and withdrawal of the rejection under § 102(b) is respectfully requested.

#### **Rejection under §103(a)**

Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Somers in view of U.S. Application No. US 2004/0248136 to Yoshizaki et al. (hereinafter “Yoshizaki”).

The Office asserts that claim 4 is drawn to an embodiment of the method of Claim 1 or 2 wherein the probe polynucleotides are labeled with fluorescent substance. The Office contends that Somers teach a method consisting essentially of the steps recited in claim 4, and that the use of fluorescent substances as detection labels in nucleic acid based assays was well known prior to the instant invention as evidenced by Yoshizaki.

In response, Applicants note that Yoshizaki is directed to a method for labeling a nucleic acid characterized in that the ratio of signal intensities of each label of the labeled nucleic acid is substantially the same (abstract of Yoshizaki). Incorporation of a fluorescent substrate is briefly and generally discussed in the “Background Art” section of Yoshizaki (paragraphs [0005], [0007], and [0009] of Yoshizaki).

As discussed above, there is nothing in Somers that teaches or suggests the claimed method for detecting a base sequence of interest in which each base sequence of interest in the sample polynucleotide is identified by one probe complementary to the base sequence of interest. Also, as indicated by the Office, Somers does not teach using a fluorescent label but rather a digoxigenin label (page 6, third paragraph of Office Action). Somers provides no reason to motivate one of ordinary skill in the art to substitute the digoxigenin label disclosed in Somers for a fluorescent label of Yoshizaki. For example, there is no teaching or suggestion in Somers that it would be advantageous to use a fluorescent label over digoxigenin. Accordingly, one of ordinary skill in the art would have no preference to use a fluorescent label over the disclosed digoxigenin label, which is well known in the art for its small size and relative ease for attaching to biological molecules, along with the availability of antibodies to target digoxigenin.

Therefore, it would not have been obvious to one of ordinary skill in the art to combine the teachings of Somers and Yoshizaki, and it would not have been obvious such combination would result in the claimed method for the detection of a base sequence of interest in a sample polynucleotide wherein each base sequence of interest in the sample polynucleotide is identified by one probe complementary to the base sequence of interest.

Accordingly, reconsideration and withdrawal of the rejection under § 103(a) is respectfully requested.

### **Claim Objections**

Claims 2 and 5-8 are objected to as being dependent upon a rejected base claim, but it is asserted would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response, Applicants note that claim 2 and 5 are directly dependent on rejected claim 1, and claims 6-8 are indirectly dependent on rejected claim 1.

Accordingly, Applicants respectfully request that the grounds of this objection be withdrawn by the Office upon withdrawal of the rejection to claim 1.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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